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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874

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EXAMINER

SIRMONS, KEVIN C

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/711,648

Applicant(s)

PONZI ET AL.

Examiner

Kevin C. Sirmons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-12, 25 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al U.S. Pat. No. 5,370,675.

Edwards discloses an injection catheter comprising: a catheter body comprising a flexible tubing having proximal and distal ends and at least one lumen therethrough (48, 154, 184, 208, 300); a tip section comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body (50, fig. 11, 186, 304)); a needle control handle at the proximal end of the catheter body (figs. 11-12, 14, 18, 26, 32-32); an injection needle extending through the tip section, catheter body, and needle control handle and having proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter upon suitable manipulation of the needle control handle (col. 14, lines 54-60, note it is the examiner's position that although not shown (figs. 4-10) inherently has a needle control handle with a proximal end attached to the needle control handle); and an electrode lead wire having a first end electrically connected to the injection needle and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (figs. 4-18, 26, 32-34 and the entire specification);

as to claims 5, 6, 7, 8 (see above listed figures); and as to claims 9-12, (see above rejection); as to claims 25, 27 and 28 (see above rejection); and as to claim 29, (fig. 4, 9, 10, 14 and 16).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 and 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Edwards et al U.S. Pat. No. 5,370,675.

Edwards discloses an injection catheter substantially as claimed however, it may not be clear to someone who is not of ordinary skill in the art that the that the first end of the electrode lead wire is connected near the proximal end or distal end of the injection needle. Therefore, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a proximal and/or distal wire connection, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. As to claims 4 and 26, (col. 42-63).

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards U.S. Pat. No. 5,370,675 in view of Edwards U.S. Pat. No. 5,599,294.

Edward discloses an injection catheter substantially as claimed except for disclosing a method for introducing a therapeutic or diagnostic agent into heart tissue of a patient.

Edwards discloses a method of using an injection catheter for introducing therapeutic or diagnostic agent into the heart tissue of a patient (col. 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Edwards device in the heart since Edwards (294) discloses that it would be readily apparent to a person skilled in the art that the device and method can be used to destroy body tissues in areas other than the prostate such as the brain, heart and/or other body cavities and tissue locations that are accessible by percutaneous or endoscopic catheters. Application of the device and method in all of these organs and tissues are intended to be included within the scope of this invention. As to claims 13 and 15, (col. 13, lines 5-18) and (col. 14, lines 1-11); as to claim 14, (see above rejection); as to claim 16, col. 3; as to claim 17-20, (see above rejections).

### *Response to Arguments*

Applicant's arguments filed 4/28/03 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the needle is longitudinally slidable within the tip section so that the distal end can extend out of **the distal end of the catheter, emphasis added**) are clearly recited in the rejected claim(s) and clearly shown in the prior art reference.

Edwards discloses a catheter (48, 154, 184, 208 and 300) with a distal end. Edwards discloses a tip section (50, Fig. 11, 186 and 304).

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As one of ordinary skill in the art would clearly recognize that the needle is longitudinally slidable within the tip section (50, Fig. 11, 186 and 304) so that its distal end can extend out the distal end of the catheter (48, 154, 184, 208 and 300), as presently claimed. Note: the claims *do not require* the distal end of the injection needle to be longitudinally slidable within the tip section so that its distal end can extend out of the *distal end of the tip section* upon suitable manipulation of the needle control handle. The claims only require that the injection needle is longitudinally slidable within the tip section so that its distal end can extend out of the distal end of the catheter.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

*KCS*  
Kevin C. Sirmons  
Patent Examiner  
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